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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/838,286	04/20/2001	Jacques Dumas	BAYER-14	9096

23599 7590 03/25/2008

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EXAMINER	
KWON, BRIAN YONG S	

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
03/25/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
09838286	4/20/2001	DUMAS ET AL.	BAYER-14

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EXAMINER
Brian-Yong S. Kwon

ART UNIT	PAPER
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DATE MAILED:

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Commissioner for Patents

-Receipt is acknowledged of Appellant's Second Reply Brief filed January 18, 2008, which papers have been placed for record in the filed.
-Appellant's arguments have been fully considered, but they are not persuasive. With respect to appellant's arguments that "Appellants do maintain most of the numerous prior art references which have cited in an IDS and made of record describe urea compounds of a similar structure and similar broad utility, including the p38 inhibitor BIRB-796. BIRB-796 has been used in clinical trials to treat various inflammatory diseases. In finding the art unpredictable, Examiner has not acknowledged or considered the broad teachings in the art relating to similar ureas with similar activity, including those relating to BIRB-796" (page 3, lines 3-8) and "the Examiner has not explained why the urea p38 inhibitor BIRB-796 is not similar to the compounds claimed and its use in clinical trials provides no guidance in using the compounds of this invention" (page 3, lines 24-26), the examiner recognizes that the breadth of the instant invention is not limited to "inflammatory diseases" as appellant's alleged, rather the instant invention is drawn to treatment of various disease conditions mediated through P38 including inflammatory diseases, infectious diseases, periodontal diseases, cardiovascular diseases, birth control, neurodegenerative diseases, endocrine disease, etc… (more than 100 different types of diseases). As the examiner pointed out repeatedly in Examiner's Answers (06/11/07 and 11/16/07) that determining if any particular compound would treat any particular diseases would undergo "undue amounts of experimentation" which requires synthesis of the compound, formulation into a suitable dosage forms, and subjecting it clinical trials with to treat said diseases conditions or to testing them in an assay known to be correlated to clinical efficacy of such treatment. Thus, coupled to the fact that claims encompass thousands of structrally diverse compounds and treatment of any and all diseaes conditions mediated through p38, it would take undue, painstaking experiementation to actually practice the full scope of the claimed invention.
-In response to appellant's arguments that "It is not necessary to perform such assays or subject theses compounds to clinical trials to satisfy 35 USC 112, first paragraph" (page 1, last para. lines 6-7), "an applicant is not required to test the claimed compounds in their final use or win approval at the FDA to satisfy the enablement requirement of USC 112, first paragraph" (page 5, lines 2-5) and "it is not necessary that each compound claimed be tested in clinical trials or win approval from FDA to meet the statutory under 35 USC 112" (page 5, lines 22-24), the Examiner respectfully submits that he never implied that FDA approval is required. As stated in the previous Examiner's Answer (page 31, lines 3-13), the examiner acknowledged that FDA approval or clinical efficacy of (all) working examples to be present in the disclosure of the invention is not required to satisfy the statue under 112, 1st paragraph. However, in analyzing the Wands factor relating the direction and guidance provided by Appellants and the state art of art at the time of the invention was made, the Examiner made the observation that Appellant have not shown that inhibiting of p38 kinase as demonstrated in the specification correlates to efficacy in the treatment of these multiple complex disorders having unrelated manifestations.
-No further commentary needed.
-Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on (571)

272-0718. The fax number for this Group is (571) 273-8300.
Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications may be obtained from Private PAIR only. For more information about PAIR system, see http://pair-direct.uspto.gov Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

/Brian-Yong S Kwon/
Primary Examiner, Art Unit 1614

PTO-90C (Rev.04-03)